

Notice of Allowability**Application No.**

09/852,100

Applicant(s)

OZENBERGER ET AL.

Examiner

Christopher J Nichols, Ph.D.

Art Unit

1647

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11 February 2004.
2. ☒ The allowed claim(s) is/are 4-8, 34-42, 45, and 46.
3. ☒ The drawings filed on 9 May 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment and Response filed 11 February 2004 has been received and entered in full.
2. The Amendment filed 19 April 2004 has been received and entered in full.
3. The Declaration concerning the ATCC Deposit filed 19 April 2004 has been received and entered in full.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

5. The Objection to the Specification as set forth in the previous Office Action (23 October 2003) at pp. 2-3 ¶4-5 is hereby *withdrawn* in view of Applicant's amendments (11 February 2004).
6. The Objection to claim 9 as set forth in the previous Office Action (23 October 2003) at pp. 3 ¶6 is *moot* in view of Applicant's cancellation of said claim (11 February 2004).
7. The Rejection of claims 4-7 under 35 U.S.C. §101 as set forth in the previous Office Action (23 October 2003) at pp. 3 ¶7 is hereby *withdrawn* in view of Applicant's amendments (11 February 2004).
8. All Objections and Rejections previously made are hereby *withdrawn*.

EXAMINER'S AMENDMENT

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9. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

Claims 1-3 (Cancelled)

Claim 4 (Previously Presented) An isolated protein comprising the amino acid of SEQ ID NO: 2.

Claim 5 (Previously Presented) An isolated protein comprising the amino acid of SEQ ID NO: 2 from amino acid 68 to amino acid 269.

Claim 6 (Previously Presented) An isolated protein comprising the amino acid sequence encoded by cDNA insert of clone BBP1-fl deposited under accession number ATCC 98617.

Claim 7 (Previously Presented) An isolated protein comprising the amino acid sequence from amino acid 185 to amino acid 217 of SEQ ID NO: 2.

Claim 8 (Previously Presented) A non-naturally occurring fusion protein comprising amino acid 185 to amino acid 217 of SEQ ID NO: 2.

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Claims 9-33 (Cancelled)

Claim 34 (Previously Presented) The fusion protein of claim 8 comprising a human β -Amyloid Peptide (BAP).

Claim 35 (Previously Presented) The fusion protein of claim 34 wherein the BAP is BAP42.

Claim 36 (Previously Presented) The fusion protein of claim 8 comprising a protein which is heterologous to SEQ ID NO: 2.

Claim 37 (Previously Presented) A fusion protein comprising the amino acid sequence of SEQ ID NO: 2 from amino acids 68 to 269 with two regions of sufficient length and hydrophobicity to transverse a cellular membrane as deposited under the accession number ATCC 98399.

Claim 38 (Previously Presented) A non-naturally occurring fusion protein comprising the amino acid sequence of SEQ ID NO: 2 linked to a peptide sequence.

Claim 39 (Previously Presented) The fusion protein of claim 8 comprising maltose binding protein (MBP), glutathione-S-transferase (GST), or thioredoxin (TRX).

Claim 40 (Previously Presented) A method for identifying compounds that modulate the binding between two proteins a β -amyloid peptide and a protein of claim 7, comprising:

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- (a) incubating a test compound in a test medium comprising a said β -amyloid peptide and a said protein of claim 7 under conditions effective for binding of said β -amyloid peptide to said protein of claim 7; and
- (b) comparing the binding of said β -amyloid peptide to said protein of claim 7 in the presence and absence of said test compound, wherein increased binding designates an activator and decreased binding designates an inhibitor of said binding.

Claim 41 (Presented Previously) A recombinant protein comprising amino acid 185 to amino acid 217 of SEQ ID NO: 2.

Claim 42 (Presented Previously) The recombinant protein of claim 41, comprising amino acid 68 to amino acid 269 of SEQ ID NO: 2.

Claim 43 (Cancelled)

Claim 44 (Cancelled)

Claim 45 (Previously Presented) A method for identifying agents that modulate the binding between ~~two proteins~~ a protein of interest and a protein of claim 41, comprising:

- (a) contacting an agent to a medium or platform which includes a said protein of interest and a said recombinant protein of claim 41; and

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(b) comparing binding of said protein of interest to said recombinant protein in the presence and absence of said agent, wherein a change in said binding indicates that said agent is a modulator of said binding.

Claim 46 (Previously Presented) A recombinant protein comprising amino acid 123 to amino acid 202 of SEQ ID NO: 2.

Claim 47 (Cancelled)

Claim 48 (Cancelled)

Authorization for this examiner's amendment was given in a telephone interview with Raymond Van Dyke (Reg. No. 34,746) on 20 April 2004.

Summary

10. Claims **4-8**, **34-42**, and **45-46** are hereby allowed.

11. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **<http://pair-direct.uspto.gov>**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).



ELIZABETH KEMMERER
PRIMARY EXAMINER

CJN

April 21, 2004